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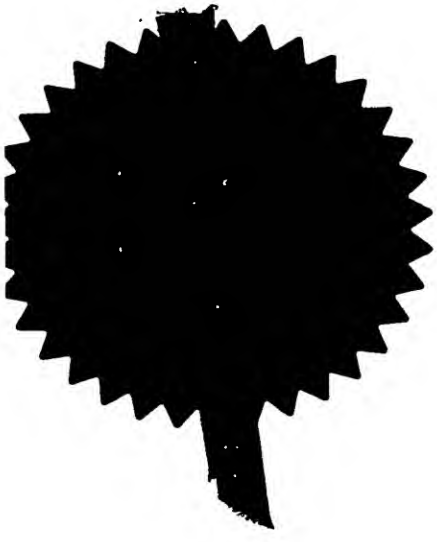

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Dated 30 September 2004

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23 SEP 2003

1. Your reference — CLA/P103545GB

2. Patent application number *(The Patent Office will fill in this part)* — 0322342.7

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Dr Reed Gamble
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TS9 7HY

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation — 8719734001

4. Title of the invention — Skin Patch

5. Name of your agent *(if you have one)*

Harrison Goddard Foote

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

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YORK
YO1 8NQ

Patents ADP number *(if you know it)* — 07914237002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

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Continuation sheets of this form	
Description	11
Claim(s)	6
Abstract	–
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Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature C. Adcocks Date 22 September 2003

12. Name and daytime telephone number of person to contact in the United Kingdom Dr C Adcocks 01904 732120

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SKIN PATCH

The invention relates to a skin patch, kit or method for reducing exposure of skin to UV radiation.

Background to the invention

Protecting individuals from sunlight is important due to the deleterious cosmetic and medical effects of sunlight on skin and subcutaneous tissues, both immediately after exposure and after prolonged and/or repeated exposure. Cosmetically, sunlight can cause reddening of the skin and repeated exposure can cause premature aging. Sunlight as cause of skin cancers, for example melanoma and squamous and basal cell carcinomas was first postulated by Thiersch in 1875 and Unna in 1894. Probably the most common type of longer term damage is basal cell carcinoma which, although seldom fatal, can be disfiguring and required medical attention. Squamous cell carcinoma although generally not fatal can spread through the body if left untreated. The most serious cancer associated with sunlight exposure is malignant melanoma. Malignant melanoma currently accounts for approximately 1% of all cancer deaths. The frequency distribution of malignant melanomas varies considerably in dependency on the geographical region. The highest worldwide incidence rate is in Australia and in the southern states of the U.S.A, with up to 40 new cases per 100,000 inhabitants each year. The incidence rate in Central Europe and in Germany is between 6 to 10 cases per 100,000 inhabitants each year.

Sun light is composed of 66% infra-red light (manifested as heat), 32% visible light and 2% ultraviolet light (UV). The component of sunlight that has been identified as

causing deleterious medical effects are wavelengths in the UV spectrum. UVA (320-400nm), UVB (280-320 nm) and UVC (200-280 nm). Both UVA and UVB ranges have been found to contribute to skin damage. UVB is the main cause of sunburn, with UVA supplementing the effects of UVB on the skin. UVA however having a longer wavelength than UVB can penetrate deeper into the skin. The UVC component of sunlight also causes deleterious medical effects, but is largely removed by the ozone layer.

In order to protect individuals from the harmful effects of the suns rays, a number of fabrics which can be manufactured into articles of clothing and also non-apparel articles such as tents, awning, crowd covers and parasols, have been developed that offer UV protection using a plethera of different technologies. For example, US 5,414,913 and 5,503,917 disclose fabrics which reduce the transmission of UVA and UVB by the alteration of the ratio of threads to apertures. The incorporation of dyes for increasing the sun protection factor (SPF) rating of a fabric is disclosed in WO 962 5549, WO 9417135 and WO 9404515. WO 02059407 discloses a fabric comprising synthetic polymers in which the fabric has been calendered or "chintzed" on at least one surface in order to improve the UV protection factors. A further method is the incorporation of UV blocking particles or absorbers into fabrics, these particles reflect, absorb and/or scatter the UV rays, such an approach is outlined in US 6.037,280 and EP 0 919 660.

According to an American Cancer Society study most non-melanoma skin cancers (e.g basal and squamous cell carcinomas) develop on sun-exposed areas of the body, like the face, ear, neck, lips, and the backs of the hands. Melanoma affects the

pigment-producing cells (melanocytes) found in the skin and can appear as a new mole, or arise from an existing mole on the skin. Moles are harmless skin growths that may be flat or protruding.

Whilst the fabrics disclosed in the prior art can be used to manufacture articles of clothing for an individual to wear and thereby limit the amount of skin exposure to UV light, it is not possible to completely cover up from exposure to the sun, particularly in countries with warm climates. If an individual has moles on exposed sites of skin such as on the face, scalp and hands it would be clinically valuable to be able to limit the amount of UV that these sites are exposed to.

A need therefore exists for the focal protection of vulnerable areas of the skin, areas for instance that are vulnerable to the development of cancer, for example moles, to exposure to UV radiation. The application of a patch also gives the users the reassurance that they specific areas of the skin are protected from UV and they therefore do not, for example, have to worry about the re-application of sun tan lotions during the day.

Statement of the invention

Therefore, according to a first aspect of the invention there is provided a skin patch comprising a first layer which is adhesive and a second layer comprising a material adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation.

The term opaque as herein used is defined as being impenetrable by a form of radiation other than visible light. The term UV radiation as herein used is defined as wavelengths in the ultra violet spectrum, UVA (320-400nm), UVB (280-320 nm) and UVC (200-280 nm).

Preferably the skin patch is opaque to UVA, UVB and UVC radiation. In an alternative embodiment of the invention the skin patch is opaque to UVA and UVB radiation. UVA and UVB radiation have been found to be the elements of the UV spectrum that cause deleterious medical effects. Whilst the UVA component has the potential to induce deleterious medical effects it is largely removed by the ozone layer. However, as the ozone layer is depleted, particularly over areas such as Australia, the need to protect against UVC radiation will increase significantly.

The first layer of the skin patch, which is the adhesive layer may be opaque to UV radiation, but it is preferably the second layer of the skin patch that is opaque to UV radiation.

A UV protection factor (UPF) below 15 is deemed "low protection", a UPF of 15 to 30 is deemed "medium protection" and a UPF greater than 30 is deemed "high protection.

Preferably the skin patch has a UPF of equal to or greater than 30. Alternatively said skin patch has a UPF in the range of from 15-30.

The protection against UV light can also be described in terms of sun protective factor (SPF). An SPF number of measured by the following equation: 100/ % transmission of UV light = SPF number. Thus a composition permitting 20% transmission has a SPF # of 5; whilst a composition permitting 10% transmission has a SPF # of 10.

The opaque property of the first and/or second layer of the skin patch is preferably as a result of a chemical or physical modification.

Even more preferably said chemical modification comprises UV blocking agents. Examples of UV blocking agents are described in US 6,037,280 which is herein incorporated by reference. UV blocking agents act as a result of deflecting, reflecting, absorbing or scattering the UV radiation. The UV radiation blocking agents are preferably inorganic, organic or metallic. Examples of such particles include, but are not limited to muscovite, phlogopite, biotite, sericite, fushitite, margarite, synthetic mica, metal oxide coated mica, coloured pigment coated mica, talc, benzotriazole e.g chlorobenzotriazoles, para-aminobenzoic acid, metal oxides, metallic hydroxides, mixed metal oxides and hydroxides, metal and mixed metal silicates and aluminosilicates, transition metal oxides and hydroxides, Ti02, Zr02, Fe2O3, natural clay, metal sulfides, non-metallic elements, ionic salts and covalent salts, powered ceramics, organic polymers for example CYASORB® (Cytec Technology Corp, USA) UV-3346, -1164, -3638, -5411 and TINUVIN® (Ciba Specialty Chemicals Holding Inc., Switzerland), natural polymers, insoluble organic materials and biomaterials, particularly UV absorbing molecules, aluminium, copper, copper-bronze, bronze-gold, silver and collagen.

Preferably said UV radiation blocking agent absorbs UV radiation and is para-aminobenzoic acid (PABA). This compound is a popular UV absorber in tanning lotions.

Preferably the UV radiation blocking agent is a particle. A binding agent may be used to bind the UV radiation blocking particle to the fabric. Examples of such binding agents include but are not limited to casein isolate, soy protein isolate, starch, starch derivatives, gums and synthetic latexes.

Preferably the UV radiation blocking agents are incorporated within a layer of the skin patch. Even more preferably still said incorporation is within interstitial spaces. Alternatively the UV radiation blocking agents are attached to a surface of a layer. Preferably this surface is an upper surface of the second layer.

Prior to addition of the above described agents to a layer, using techniques known to those skilled in the art, the agents may be in tablet form, delivered from a sachet, bottle, tube or other mechanisms for delivering such agents in a concentrated form, such as a paste.

In an alternative embodiment of the invention at least one of said first or second layers of said skin patch is opaque to UV radiation as a result of a physical change within said layer.

The permeability of for instance a fabric is an important factor in opaqueness to UV radiation. Conventionally a fabric can be made relatively UV-opaque by providing a relatively tight weave or a very high thread count, or by coating the fabric.

Calendering or chintzing is a known technique for improving the wind resistance of certain materials, for reducing the leakage of fibres through a fabric from a fibrous insulation layer or for changing the appearance of certain fabrics. Calendering or chintzing is performed by applying heat and pressure to at least one surface of a fabric. Calendered surfaces are easily identified by the characteristic plastic deformation of the surface. The calendaring temperature is preferably maintained in a range of 140°C to 195°C. The calendering pressure is preferably 50 tonnes/sq.inch (6.5×10^6 N/m^2) (+/-(10%). And the calendaring is preferably performed at a speed in the range of from 12 to 18 meters per minute.

Therefore, preferably said structural change is achieved by calendering as described in PCT/GB02/00317, as herein incorporated by reference. Even more preferably said second layer is calendered on at least one surface.

Alternative methods of inducing such a structural change to enhance the UV protection factors include but are not limited to sanding followed by jet laundering as disclosed in US 5,503,917 or 'wrinkling' of the fabric as disclosed in EP 0919 660. Specific weaves, twists or bends of yarns or fabrics which have been developed to effectively screen UV radiation is disclosed in US 4,861,651.

Moles on the skin have been shown to be prone to developing into melanoma. It is therefore particularly advantageous to be able to apply a skin patch according to the invention directly above such a mole. However, it is desirable that the adhesive itself is not brought into direct contact with the mole as this may be potentially harmful to the mole, particularly when the patch is removed. Preferably therefore the adhesive is provided at a peripheral edge of the skin patch. Even more preferably still, the skin patch is substantially circular and the adhesive is provided around the peripheral circumference of the patch.

Even more preferably said adhesive is provided with a releasable protective layer, which is removed only when the skin patch is to be applied to the skin.

Preferably the second layer of the skin patch substantially overlies the first layer. Even more preferably the first layer comprises a substantially single thickness fabric. The term 'single thickness fabric' is defined as a single woven, non-woven or knitted layer of textile filaments. Even more preferably still said second layer comprises a section of tape. The skin patch may be manufactured as a single piece of tape to which an adhesive is applied.

It may be desirable to the user to apply the skin patch to visible areas of the skin, such as the head, neck and scalp. In order to render the skin patches as unobtrusive as possible on the user's skin it is preferable that the skin patch is transparent to visible light. The use of a transparent material which is impermeable to UV penetration has been used in the field of contact lenses, contact lenses have been developed with

incorporated UV blockers and are designed to complement sunglass use as an added protection.

In an alternative embodiment of the invention the second layer of the skin patch comprises a gel. Preferably this gel rests above the mole when the skin patch is applied. In this embodiment the first layer may comprises a fabric such as a piece of tape which is provided with an adhesive. The gel comprises UV blocking agents as described in the first embodiment of the invention.

In a second aspect of the invention there is provided a method of manufacturing a skin patch wherein said skin patch comprises a first layer which is adhesive and a second layer adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation; comprising the steps of;

i) providing a first and second layer wherein at least one of said layers is opaque to UV radiation or capable or being rendered opaque to UV radiation;

ii) bringing into contact said layers in (i).

Preferably the second layer comprises a single thickness fabric. Even more preferably still the single thickness fabric is a section of tape. Alternatively the second layer comprises a gel.

Even more preferably a releasable protective layer is applied to the adhesive to prevent the skin patch sticking to other materials prior to application to the skin.

Even more preferably still the skin patch may also be inserted into a wrapper for storage prior to use.

The opaqueness is a result of a modification of at least one layer of the skin patch, said modification being selected from the group consisting of chemical or physical modification.

Examples, which are not limiting of chemical and physical modifications are outlined above. Preferably said a chemical modification comprises the addition of UV radiation blocking agents to at least one layer of said skin patch. Preferably said physical modification is as a result of calendaring of at least one layer of said skin patch.

In a third aspect of the invention there is provided a method of reducing skin exposure to UV radiation comprising the steps of;

i) providing a skin patch comprising a first layer which is adhesive and a second layer adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation;

ii) applying said patch to the skin with the adhesive layer contacting said skin.

In a further aspect of the invention there is provided a method of preventing skin cancer as a result of exposure to UV radiation comprising the steps if;

i) providing a skin patch comprising a first layer which is adhesive and a second layer adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation;

ii) applying said patch to an area of skin with the adhesive layer contacting said skin.

Preferably said skin cancer is selected from the group consisting of basal cell carcinoma, squamous cell carcinoma or malignant melanoma.

Preferably said area of skin is specifically susceptible to UV radiation. Even more preferably still said area of skin is a mole.

According to a still further aspect of the invention there is provided a kit comprising a plurality of skin patches of varying sizes.

Claims

1. A skin patch comprising a first layer which is adhesive and a second layer comprising a material adjacent to said first layer characterised in that at least one of said first or second layers is opaque to a UV radiation.

2. A skin patch according to claim 1, wherein said second layer is opaque to a UV radiation.

3. A skin patch according to claims 1 or 2, wherein said UV radiation is selected from the group consisting of (320-400nm), UVB (280-320 nm) and UVC (200-280 nm) radiation.

4. A skin patch according to any of claims 1 to 3, wherein said skin patch has a UV protection factor (UPF) greater or equal to 30.

5. A skin patch according to any of claims 1 to 3, wherein said skin patch has a UV protection factor (UPF) in the range of from 15 to 30.

6. A skin patch according to any of claims 1 to 5, wherein at least one layer comprises a modification which results in the layer being opaque to UV radiation, such modification selected from the group consisting of; chemical modification or physical modification.

7. A skin patch according to claim 6, wherein said chemical modification comprises the addition of UV radiation blocking agents.

8. A skin patch according to claim 7, wherein said second layer comprises said UV radiation blocking agents.

9. A skin patch according to claims 7 or 8, wherein said UV radiation blocking agents is incorporated into a layer.

10. A skin patch according to claim 9, wherein said incorporation is with interstitial spaces within a layer.

11. A skin patch according to claims 7 or 8, wherein said UV radiation blocking agents is attached to a surface of a layer

12. A skin patch according to any of claims 7 to 11, wherein said UV radiation blocking agents act as a result of deflecting, reflecting, absorbing or scattering the UV radiation.

13. A skin patch according to any of claims 7-12, wherein said UV radiation blocking agents are selected from the group consisting of; inorganic, organic or metallic agents.

14. A skin patch according to claim 7, wherein said physical modification is a result of calendaring.

15. A skin patch according any of claim 1 to 14, wherein said adhesive is provided at a peripheral edge of said skin patch.

16. A skin patch according to any of claims 1 to 15, wherein said adhesive is provided with a releasable protective layer.

17. A skin patch according to any of claims 1 to 16, wherein said second layer substantially overlies said first layer.

18. A skin patch according to any of claims 1 to 17, wherein said material comprises a substantially single thickness fabric.

19. A skin patch according to claim 18, wherein said material comprises a section of tape.

20. A skin patch according to any of claims 1 to 17, wherein said material comprises a gel.

21. A skin patch according to any of claims 1 to 20, wherein said skin patch is substantially circular.

22. A skin patch according to any of claims 1 to 21, wherein said skin patch is substantially waterproof.

23. A skin patch according to any of claims 1 to 22, wherein said skin patch is transparent to visible light.

24. A method of manufacturing a skin patch wherein said skin patch comprises a first layer which is adhesive and a second layer adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation comprising the steps of;

i) providing a first and second layer wherein at least one of said layers is opaque to UV radiation or capable or being rendered opaque to UV radiation;

ii) bringing into contact said layers in (i).

25. A method according to claim 24, wherein said second layer is a single thickness fabric.

26. A method according to claim 25, wherein said single thickness fabric is a section of tape.

27. A method according to claim 24, wherein said second layer is a gel.

28. A method according to any of claims 24 to 27, wherein a releasable protective layer is applied to the adhesive.

29. A method according to any of claims 24 to 28, wherein said opaqueness is a result of a modification of at least one layer, said modification being selected from the group consisting of chemical or physical modification.

30. A method according to any of claims 24 to 29, wherein said chemical modification comprises UV radiation blocking agents.

31. A method according to any of claims 24 to 29, wherein said physical modification is as a result of calendering.

32. A method of reducing skin exposure to UV radiation comprising the steps of;

i) providing a skin patch comprising a first layer which is adhesive and a second layer adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation;

ii) applying said patch to the skin with the adhesive layer contacting said skin.

33. A method of preventing skin cancer as a result of exposure to UV radiation comprising the steps if;

i) providing a skin patch comprising a first layer which is adhesive and a second layer adjacent to said first layer characterised in that at least one of said first or second layers is opaque to UV radiation;

ii) applying said patch to the skin with the adhesive layer contacting said skin.

34. A method of preventing skin cancer according to claim 33, wherein said skin cancer is selected from the group consisting of basal cell carcinoma, squamous cell carcinoma, malignant melanoma.

35. A method according to claims 33 or 34, wherein said skin patch is applied directly to a mole.

36. A kit comprising a plurality of skin patches of varying sizes according to any of claims 1 to 23.

37. A skin patch, kit or method as herein described with reference to the associated description.

PCT/GB2004/004034